



## **DEPARTMENT OF HEALTH AND HUMAN SERVICES**

### **Office of the Secretary**

#### **42 CFR Part 3**

### **Centers for Medicare & Medicaid Services**

#### **42 CFR Parts 402, 403, 411, 412, 422, 423, 460, 483, 488, and 493**

### **Office of the Inspector General**

#### **42 CFR Part 1003**

### **Office of the Secretary**

#### **45 CFR Parts 79, 93, 102, 147, 150, 155, 156, 158, and 160**

### **Administration for Children and Families**

#### **45 CFR Part 303**

#### **RIN 0991-AC0**

### **Adjustment of Civil Monetary Penalties for Inflation and the Annual Civil Monetary Penalties Inflation Adjustment for 2021**

**AGENCY:** Office of the Assistant Secretary for Financial Resources, Department of Health and Human Services (HHS).

**ACTION:** Final rule.

**SUMMARY:** This final rule finalizes the provisions of the September 6, 2016 interim final rule that adjusts for inflation the maximum civil monetary penalty (CMP) amounts for all agencies within the Department of Health and Human Services (HHS) and updates certain agency-specific regulations. It also updates our required annual inflation-related increases to the CMP amounts in our regulations, under the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015; adds references to new penalty authorities; and reflects technical changes to correct errors.

**DATES:** *Effective date:* This final rule is effective [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

*Applicability date:* The adjusted civil monetary penalty amounts apply to penalties assessed on or after [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER], if the violation occurred on or after November 2, 2015.

**FOR FURTHER INFORMATION CONTACT:** David Dasher, Deputy Assistant Secretary, Office of Acquisitions, Office of the Assistant Secretary for Financial Resources, Room 536-H, Hubert Humphrey Building, 200 Independence Avenue S.W., Washington D.C. 20201; 202-205-0706.

## **SUPPLEMENTARY INFORMATION:**

### **I. Background**

The Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of Pub. L. 114-74) (the “2015 Act”) amended the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101-410, 104 Stat. 890 (1990)), which is intended to improve the effectiveness of civil monetary penalties (CMPs) and to maintain the deterrent effect of such penalties, requires agencies to adjust the civil monetary penalties for inflation annually.

The Department of Health and Human Services (HHS) lists the CMP authorities and the amounts administered by all of its agencies in tabular form in 45 CFR 102.3, which was issued in an interim final rule published in the September 6, 2016, **Federal Register** (81 FR 61538). Annual adjustments were subsequently published on February 3, 2017 (82 FR 9175), October 11, 2018 (83 FR 51369), November 5, 2019 (84 FR 59549), and January 17, 2020 (85 FR 2869).

### **II. Provisions of the Final Rule**

#### *A. Finalization of the September 6, 2016 Interim Final Rule*

In the September 6, 2016 **Federal Register** (81 FR 61538), HHS issued a department-wide interim final rule (IFR) titled “Adjustment of Civil Monetary Penalties for Inflation” that established new regulations at 45 CFR part 102 to adjust for inflation the maximum CMP

amounts for the various CMP authorities for all agencies within the Department. HHS took this action to comply with the Federal Civil Penalties Inflation Adjustment Act of 1990 (the Inflation Adjustment Act) (28 U.S.C. 2461 note 2(a)), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (section 701 of the Bipartisan Budget Act of 2015, (Pub. L. 114–74), enacted on November 2, 2015). In addition, the September 2016 IFR included updates to certain agency-specific regulations to reflect the new provisions governing the adjustment of civil monetary penalties for inflation in 45 CFR part 102.

One of the purposes of the Inflation Adjustment Act was to create a mechanism to allow for regular inflationary adjustments to federal civil monetary penalties. Section 2(b)(1) of the Inflation Adjustment Act. The 2015 amendments removed an inflation update exclusion that previously applied to the Social Security Act as well as to the Occupational Safety and Health Act. The 2015 amendments also “reset” the inflation calculations by excluding prior inflationary adjustments under the Inflation Adjustment Act and requiring agencies to identify, for each penalty, the year and corresponding amount(s) for which the maximum penalty level or range of minimum and maximum penalties was established (that is, originally enacted by Congress) or last adjusted other than pursuant to the Inflation Adjustment Act. In accordance with section 4 of the Inflation Adjustment Act, agencies were required to: (1) adjust the level of civil monetary penalties with an initial “catch-up” adjustment through an interim final rulemaking to take effect by August 1, 2016; and (2) make subsequent annual adjustments for inflation.

In the September 2016 interim final rule, HHS adopted new regulations at 45 CFR part 102 to govern adjustment of civil monetary penalties for inflation. The regulation at 45 CFR 102.1 provides that part 102 applies to each statutory provision under the laws administered by HHS (including the Centers for Medicare & Medicaid Services (CMS)) concerning CMPs, and that the regulations in part 102 supersede existing HHS regulations setting forth CMP amounts. The CMPs and the adjusted penalty amounts administered by all HHS agencies are listed in tabular form in 45 CFR 102.3. In addition to codifying the adjusted

penalty amounts identified in §102.3, the HHS-wide interim final rule included several technical conforming updates to certain agency-specific regulations, including various CMS regulations, to identify their updated information, and incorporate a cross-reference to the location of HHS-wide regulations.

In the September 12, 2017 **Federal Register** (82 FR 42748), CMS published a correcting amendment that corrected a limited number of technical and typographical errors identified in the CMS provisions of the September 6, 2016 IFR.

The Medicare provisions included in the September 2016 IFR are subject to requirements of section 1871(a) of the Social Security Act (the Act) which sets forth certain procedures for promulgating regulations necessary to carry out the administration of the insurance programs under Title XVIII of the Act. Section 1871(a)(3)(A) of the Act requires the Secretary, in consultation with the Director of the Office of Management and Budget (OMB), to establish a regular timeline for the publication of final regulations based on the previous publication of a proposed rule or an interim final rule. In accordance with section 1871(a)(3)(B) of the Act, such timeline may vary among different rules, based on the complexity of the rule, the number and scope of the comments received, and other relevant factors. However, the timeline for publishing the final rule cannot exceed 3 years from the date of publication of the proposed or interim final rule, unless there are exceptional circumstances. After consultation with the Director of OMB, the Secretary published a notice, which appeared in the December 30, 2004 **Federal Register** (69 FR 78442), establishing a general 3-year timeline for publishing Medicare final rules after the publication of a proposed or interim final rule.

Because the conforming changes to the Medicare provisions were part of a larger, omnibus departmental interim final rule, we inadvertently missed setting a target date for the final rule to make permanent the changes to the Medicare regulations in accordance with section 1871(a)(3)(A) of the Act and the procedures outlined in the December 2004 notice. Consistent with section 1871(a)(3)(C) of the Act, we published notices of continuation extending the

effectiveness of the technical conforming changes to the Medicare regulations that were implemented through interim final rule and to allow time to publish a final rule (see the January 2, 2020 (85 FR 7) and September 8, 2020 (85 FR 55385) continuation documents). The extended time was needed to allow for coordination between CMS and the Department to issue a final rule and to avoid the potential for confusion between 45 CFR part 102, which established the civil monetary payment amounts, and the Medicare regulations subject to the timing requirements in section 1871(a)(3)(C) of the Act, which would otherwise cause the regulation to revert to the language that was used prior to the Inflation Adjustment Act.

In this final rule, we are finalizing the provisions of the September 6, 2016 IFR without modification. Because the provisions were established via interim final rulemaking, finalizing the provisions is pro forma for all agencies except CMS. Given the statutory requirements specified previously, finalization of the September 2016 IFR permanently establishes the interim final regulatory provisions for the Medicare program.

#### *B. Calculation of Annual Inflation Adjustment*

The annual inflation adjustment for each applicable CMP is determined using the percent increase in the Consumer Price Index for all Urban Consumers (CPI-U) for the month of October of the year in which the amount of each CMP was most recently established or modified. In the December 23, 2020, Office of Management and Budget (OMB) Memorandum for the Heads of Executive Agencies and Departments, M-21-10, “Implementation of the Penalty Inflation Adjustments for 2021, Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015,” OMB published the multiplier for the required annual adjustment. The cost-of-living adjustment multiplier for 2021, based on the CPI-U for the month of October 2020, not seasonally adjusted, is 1.01182. The multiplier is applied to each applicable penalty amount that was updated and published for fiscal year (FY) 2020 and is rounded to the nearest dollar.

#### *C. Other Revisions*

In addition to the inflation adjustments for 2021, this final rule updates the table in 45 CFR 102.3 to add references to new, applicable civil money penalty authorities that were established or implemented since the publication of the January 17, 2020 update and that are being updated in this rule. The rule also corrects several technical errors to regulatory references in the table and updates descriptions for clarification and accuracy.

First, a CMS final rule, “Medicare and Medicaid Programs: CY 2020 Hospital Outpatient PPS Policy Changes and Payment Rates and Ambulatory Surgical Center Payment System Policy Changes and Payment Rates. Price Transparency Requirements for Hospitals to Make Standard Charges Public” (84 FR 65524, November 27, 2019), effective January 1, 2021, finalized a new provision, codified at 45 CFR 180.90. That section establishes CMPs associated with a hospital’s noncompliance with price transparency disclosure and display requirements, and the table has been modified to reflect this requirement.

Second, section 3202(b) of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) (Pub. L. 116-136) added a requirement that each provider of a diagnostic test for COVID-19 make public the cash price for such test on the provider’s public internet site, and authorized the Secretary to impose a CMP on a provider that fails to comply. Rulemaking entitled “Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency” (85 FR 71142, November 6, 2020) implemented this statutory requirement by establishing a provision at 45 CFR 182.70, allowing for imposition of a CMP, and the table has been modified to reflect this requirement.

Third, in a CMS interim final rule with comment period entitled “Medicare and Medicaid Programs, Clinical Laboratory Improvement Amendments (CLIA), and Patient Protection and Affordable Care Act; Additional Policy and Regulatory Revisions in Response to the COVID-19 Public Health Emergency” (85 FR 54873 through 54874, September 2, 2020), CMS established requirements for all CLIA laboratories to report COVID-19 test results to the Secretary in such form and manner, and at such timing and frequency, as the Secretary may prescribe during the

COVID-19 Public Health Emergency. Failure to report test results as required results in condition level deficiencies for which CMPs or other penalties may apply. The table has been modified to reflect this requirement. Also in this interim final rule, CMS codified new enforcement requirements at 42 CFR 488.447 establishing CMP amounts that may be imposed against long term care facilities that fail to report COVID-19 related data as required in 42 CFR 483.80(g)(1) and (2). The table has been modified to reflect these requirements.

Finally, the following technical errors were identified and are corrected in the table at 45 CFR 102.3:

- The regulatory reference of 42 CFR. 1003.210(a)(5) implementing 42 U.S.C. 1395cc(g) which was inadvertently omitted from the regulation and is added.
- The two descriptions of 42 U.S.C. 1395dd(d)(1) are revised for more accuracy because penalties for a responsible physician, unlike penalties for a hospital, are not tied to the number of beds in the hospital (see 42 U.S.C. 1395dd(d)(1)(B)).
- The first description tied to 42 U.S.C. 1395mm(i)(6)(B)(i) is revised from “is such plan” to “if such plan”.
- The regulatory references tied to 42 U.S.C. 1395ss(a)(2), (p)(8), (p)(9)(C), (q)(5)(C), (r)(6)(A), (s)(4), (t)(2) incorrectly referred to 42 CFR part 405 and are corrected to refer to 42 CFR part 402.
- The first set of regulatory references tied to 42 U.S.C. 1395ss(p)(8) are expanded to also include 42 CFR 402.105(f)(2), which was inadvertently omitted, and the corresponding description is revised to replace “any person” with “someone other than issuer” for greater accuracy and clarification.
- The description for the second set of regulatory references tied to 42 U.S.C. 1395ss(p)(8) is revised to replace “any person” with “an issuer” for greater accuracy and clarification.

- The first set of regulatory references tied to 42 U.S.C. 1395ss(p)(9)(C) are expanded to also include 42 CFR 402.105(f)(3) and (4), which were inadvertently omitted, and the corresponding description is revised to replace “any person” with “someone other than issuer” for greater accuracy and clarification.

- The description for the second set of regulatory references tied to 42 U.S.C. 1395ss(p)(9)(C) is revised to replace “any person” with “an issuer” for greater accuracy and clarification.

- The description for 42 U.S.C. 18081(c)(2) is being revised to “Failure to comply with ACA requirements related to risk adjustment, reinsurance, risk corridors, Exchanges (including QHP standards) and other ACA Subtitle D standards; Penalty for violations of rules or standards of behavior associated with issuer compliance with risk adjustment, reinsurance, risk corridors, Exchanges (including QHP standards) and other ACA Subtitle D standards. (42 U.S.C. 300gg-22(b)(2)(C))” for greater accuracy and clarification.

- Reference to the existing CMPs authorized under 42 U.S.C. 1395m-1(a) and 42 CFR 414.504(e) for a reporting entity that has failed to report or made a misrepresentation or omission in reporting applicable information was inadvertently omitted from the prior annual updates and the regulation is modified to include this authority and the 2021 adjusted amount. CMS, in separate rulemaking, made the initial catch-up adjustment for this amount in accordance with the 2015 Act on June 23, 2016 (81 FR 41036, 41069) which was \$10,017, and noted that subsequent inflationary adjustments would be made to this amount annually.

++ The adjusted amounts applying the multiplier for each year beginning in 2017 through 2020<sup>1</sup> are as follows:

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<sup>1</sup> The published multiplier for 2017 is 1.01636 (M-17-11, Implementation of the 2017 annual adjustment pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, published December 16, 2016); for 2018 it is 1.02041 (M-18-03, Implementation of Penalty Inflation Adjustments for 2018 pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, published December 15, 2017); for 2019 it is 1.02522 (M-19-04, Implementation of Penalty Inflation Adjustments for 2019 pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, published December 14, 2018); and for 2020 it is 1.01764 (M-20-05, Implementation of Penalty Inflation Adjustments for 2020 pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015, published December 16, 2019).



-- The 2017 adjusted amount is \$10,181 ( $\$10,017 \times 1.01636$ ).

-- The 2018 adjusted amount is \$10,389 ( $\$10,181 \times 1.02041$ ).

-- The 2019 adjusted amount is \$10,651 ( $\$10,389 \times 1.02522$ ).

--The 2020 adjusted amount is \$10,839 ( $\$10,651 \times 1.01764$ ).

++ The 2021 adjusted amount is calculated by applying the 2021 multiplier to \$10,839 and this adjusted amount is reflected in the table of the regulation at 45 CFR 102.3.

### **III. Statutory and Executive Order Reviews and Waiver of Proposed Rulemaking**

The 2015 Act requires Federal agencies to publish annual penalty inflation adjustments notwithstanding section 553 of the Administrative Procedure Act (APA).

Section 4(a) of the 2015 Act directs Federal agencies to publish annual adjustments no later than January 15<sup>th</sup> of each year thereafter. In accordance with section 553 of the APA, most rules are subject to notice and comment and are effective no earlier than 30 days after publication in the **Federal Register**. However, section 4(b)(2) of the 2015 Act provides that each agency shall make the annual inflation adjustments “notwithstanding section 553” of the APA.

According to OMB’s Memorandum M-21-10, the phrase “notwithstanding section 553” in section 4(b)(2) of the 2015 Act means that “the public procedure the APA generally requires (that is, notice, an opportunity for comment, and a delay in effective date) is not required for agencies to issue regulations implementing the annual adjustment.”

Consistent with the language of the 2015 Act and OMB’s implementation guidance, the inflation adjustments set out in this rule is not subject to notice and an opportunity for public comment and will be effective immediately upon publication. Additionally, HHS finds that notice and comment procedures would be impracticable and unnecessary under the APA for making the statutorily required inflation updates to newly established penalty amounts and for the ministerial and technical changes in this rule. In addition, HHS is waiving notice and comment for the non-substantive technical corrections set out in this final rule. HHS finds good cause for issuing these changes as a final rule without prior notice and comment because these

changes only update the regulation to add the new CMP authorities that will be adjusted in accordance with the 2015 Act which were implemented since the last update and to add additional technical clarifying edits to descriptions and correcting inadvertent omissions and typographical errors. For these same reasons HHS also finds good cause to make the final rule effective upon publication.

Pursuant to OMB Memorandum M-21-10, HHS has determined that the annual inflation adjustment to the civil monetary penalties in its regulations does not trigger any requirements under procedural statutes and Executive Orders that govern rulemaking procedures.

#### **IV. Effective and Applicability Dates**

This rule is effective on the date specified in the **DATES** section of this final rule. The adjusted civil monetary penalty amounts apply to penalties assessed on or after date specified in the **DATES** section of this final rule, if the violation occurred on or after November 2, 2015. If the violation occurred before November 2, 2015, or a penalty was assessed before September 6, 2016, the pre-adjustment civil penalty amounts in effect before September 6, 2016, will apply.

#### **List of Subjects in 45 CFR Part 102**

Administrative practice and procedure, Penalties.

For reasons discussed in the preamble, the Department of Health and Human Services adopts the interim final rule published September 6, 2016, at 81 FR 61537, as final with the following changes to 45 CFR part 102:

## **PART 102 – ADJUSTMENT OF CIVIL MONETARY PENALTIES FOR INFLATION**

1. The authority citation for part 102 continues to read as follows:

**Authority:** Public Law 101-410, Sec. 701 of Public Law 114-74, 31 U.S.C. 3801-3812.

2. Amend § 102.3 by revising table 1 to read as follows:

### **§ 102.3 Penalty adjustment and table.**

\* \* \* \* \*

**TABLE 1 TO §102.3 -- CIVIL MONETARY PENALTY AUTHORITIES ADMINISTERED BY HHS**

<b>U.S.C. Section(s)</b>	<b>CFR<sup>1</sup></b>	<b>HHS Agency</b>	<b>Description<sup>2</sup></b>	<b>Date of Last Penalty Figure or Adjustment<sup>3</sup></b>	<b>2020 Maximum Adjusted Penalty (in \$)</b>	<b>2021 Maximum Adjusted Penalty<sup>4</sup> (in \$)</b>
21 U.S.C.:						
333(b)(2)(A)		FDA	Penalty for violations related to drug samples resulting in a conviction of any representative of manufacturer or distributor in any 10-year period.	2020	107,050	108,315
333(b)(2)(B)		FDA	Penalty for violation related to drug samples resulting in a conviction of any representative of manufacturer or distributor after the second conviction in any 10-year period.	2020	2,184,670	2,210,493
333(b)(3)		FDA	Penalty for failure to make a report required by 21 U.S.C. 353(d)(3)(E) relating to drug samples.	2020	214,097	216,628
333(f)(1)(A)		FDA	Penalty for any person who violates a requirement related to devices for each such violation.	2020	28,914	29,256
		FDA	Penalty for aggregate of all violations related to devices in a single proceeding.	2020	1,927,676	1,950,461
333(f)(2)(A)		FDA	Penalty for any individual who introduces or delivers for introduction into interstate commerce food that is adulterated per 21 U.S.C. 342(a)(2)(B) or any individual who does not comply with a recall order under 21 U.S.C. 350I.	2020	81,284	82,245
		FDA	Penalty in the case of any other person (other than an individual) for such introduction or delivery of adulterated food.	2020	406,419	411,223
		FDA	Penalty for aggregate of all such violations related to adulterated food adjudicated in a single proceeding.	2020	812,837	822,445
333(f)(3)(A)		FDA	Penalty for all violations adjudicated in a single proceeding for any person who violates 21 U.S.C. 331(jj) by failing to submit the certification required by 42 U.S.C. 282(j)(5)(B) or knowingly submitting a false certification; by failing to submit clinical trial information under 42 U.S.C. 282(j); or by submitting clinical trial information under 42 U.S.C. 282(j) that is false or misleading in any particular under 42 U.S.C. 282(j)(5)(D)	2020	12,316	12,462
333(f)(3)(B)		FDA	Penalty for each day any above violation is not corrected after a 30-day period following notification until the violation is corrected.	2020	12,316	12,462
333(f)(4)(A)(i)		FDA	Penalty for any responsible person that violates a requirement of 21 U.S.C. 355(o) (post-marketing studies, clinical trials, labeling), 21 U.S.C. 355(p) (risk evaluation and mitigation (REMS)), or 21 U.S.C. 355-1 (REMS)	2020	307,923	311,563
		FDA	Penalty for aggregate of all such above violations in a single proceeding.	2020	1,231,690	1,246,249

U.S.C. Section(s)	CFR <sup>1</sup>	HHS Agency	Description <sup>2</sup>	Date of Last Penalty Figure or Adjustment <sup>3</sup>	2020 Maximum Adjusted Penalty (in \$)	2021 Maximum Adjusted Penalty <sup>4</sup> (in \$)
333(f)(4)(A)(ii)		FDA	Penalty for REMS violation that continues after written notice to the responsible person for the first 30-day period (or any portion thereof) the responsible person continues to be in violation.	2020	307,923	311,563
		FDA	Penalty for REMS violation that continues after written notice to responsible person doubles for every 30-day period thereafter the violation continues, but may not exceed penalty amount for any 30-day period.	2020	1,231,690	1,246,249
		FDA	Penalty for aggregate of all such above violations adjudicated in a single proceeding.	2020	12,316,908	12,462,494
333(f)(9)(A)		FDA	Penalty for any person who violates a requirement which relates to tobacco products for each such violation.	2020	17,857	18,068
		FDA	Penalty for aggregate of all such violations of tobacco product requirement adjudicated in a single proceeding.	2020	1,190,433	1,204,504
333(f)(9)(B)(i)(I)		FDA	Penalty per violation related to violations of tobacco requirements.	2020	297,609	301,127
		FDA	Penalty for aggregate of all such violations of tobacco product requirements adjudicated in a single proceeding.	2020	1,190,433	1,204,504
333(f)(9)(B)(i)(II)		FDA	Penalty in the case of a violation of tobacco product requirements that continues after written notice to such person, for the first 30-day period (or any portion thereof) the person continues to be in violation.	2020	297,609	301,127
		FDA	Penalty for violation of tobacco product requirements that continues after written notice to such person shall double for every 30-day period thereafter the violation continues, but may not exceed penalty amount for any 30-day period.	2020	1,190,433	1,204,504
		FDA	Penalty for aggregate of all such violations related to tobacco product requirements adjudicated in a single proceeding.	2020	11,904,335	12,045,044
333(f)(9)(B)(ii)(I)		FDA	Penalty for any person who either does not conduct post-market surveillance and studies to determine impact of a modified risk tobacco product for which the HHS Secretary has provided them an order to sell, or who does not submit a protocol to the HHS Secretary after being notified of a requirement to conduct post-market surveillance of such tobacco products.	2020	297,609	301,127
		FDA	Penalty for aggregate of for all such above violations adjudicated in a single proceeding.	2020	1,190,433	1,204,504
333(f)(9)(B)(ii)(II)		FDA	Penalty for violation of modified risk tobacco product post-market surveillance that continues after written notice to such person for the first 30-day period (or any portion thereof) that the person continues to be in violation.	2020	297,609	301,127
		FDA	Penalty for post-notice violation of modified risk tobacco product post-market surveillance shall double for every 30-day period thereafter that the tobacco product requirement violation continues for any 30-day period, but may not exceed penalty amount for any 30-day period.	2020	1,190,433	1,204,504
			Penalty for aggregate above tobacco product requirement violations adjudicated in a single proceeding.	2020	11,904,335	12,045,044
333(g)(1)		FDA	Penalty for any person who disseminates or causes another party to disseminate a direct-to-consumer advertisement that is false or misleading for the first such violation in any 3-year period.	2020	307,923	311,563
			Penalty for each subsequent above violation in any 3-year period.	2020	615,846	623,125
333 note		FDA	Penalty to be applied for violations of 21 U.S.C. 387f(d)(5) or of violations of restrictions on the sale or distribution of tobacco products promulgated under 21 U.S.C. 387f(d) (e.g., violations of regulations in 21 CFR part 1140) with respect to a retailer with an approved training program in the case of a second regulation violation within a 12-month period.	2020	297	301
		FDA	Penalty in the case of a third violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 24-month period.	2020	594	601
		FDA	Penalty in the case of a fourth violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 24-month period.	2020	2,381	2,409
		FDA	Penalty in the case of a fifth violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 36-month period.	2020	5,952	6,022
		FDA	Penalty in the case of a sixth or subsequent violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 48-month period as determined on a case-by-case basis.	2020	11,904	12,045
		FDA	Penalty to be applied for violations of 21 U.S.C. 387f(d)(5) or of violations of restrictions on the sale or distribution of tobacco products promulgated under 21 U.S.C. 387f(d) (e.g., violations of regulations in 21 CFR part 1140) with respect to a retailer that does not have an approved training program in the case of the first regulation violation.	2020	297	301

U.S.C. Section(s)	CFR <sup>1</sup>	HHS Agency	Description <sup>2</sup>	Date of Last Penalty Figure or Adjustment <sup>3</sup>	2020 Maximum Adjusted Penalty (in \$)	2021 Maximum Adjusted Penalty <sup>4</sup> (in \$)
		FDA	Penalty in the case of a second violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 12-month period.	2020	594	601
		FDA	Penalty in the case of a third violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 24-month period.	2020	1,191	1,205
		FDA	Penalty in the case of a fourth violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 24-month period.	2020	2,381	2,409
		FDA	Penalty in the case of a fifth violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 36-month period.	2020	5,952	6,022
		FDA	Penalty in the case of a sixth or subsequent violation of 21 U.S.C. 387f(d)(5) or of the tobacco product regulations within a 48-month period as determined on a case-by-case basis.	2020	11,904	12,045
335b(a)		FDA	Penalty for each violation for any individual who made a false statement or misrepresentation of a material fact, bribed, destroyed, altered, removed, or secreted, or procured the destruction, alteration, removal, or secretion of, any material document, failed to disclose a material fact, obstructed an investigation, employed a consultant who was debarred, debarred individual provided consultant services.	2020	453,711	459,074
		FDA	Penalty in the case of any other person (other than an individual) per above violation.	2020	1,814,843	1,836,294
360pp(b)(1)		FDA	Penalty for any person who violates any such requirements for electronic products, with each unlawful act or omission constituting a separate violation.	2020	2,976	3,011
		FDA	Penalty imposed for any related series of violations of requirements relating to electronic products.	2020	1,014,390	1,026,380
42 U.S.C.				2020		
262(d)		FDA	Penalty per day for violation of order of recall of biological product presenting imminent or substantial hazard.	2020	233,313	236,071
263b(h)(3)		FDA	Penalty for failure to obtain a mammography certificate as required.	2020	18,149	18,364
300aa-28(b)(1)		FDA	Penalty per occurrence for any vaccine manufacturer that intentionally destroys, alters, falsifies, or conceals any record or report required.	2020	233,313	236,071
256b(d)(1)(B)(vi)		HRSA	Penalty for each instance of overcharging a 340B covered entity.	2020	5,883	5,953
299c-(3)(d)		AHRQ	Penalty for an establishment or person supplying information obtained in the course of activities for any purpose other than the purpose for which it was supplied.	2020	15,299	15,480
653(l)(2)	45 CFR 303.21(f)	ACF	Penalty for Misuse of Information in the National Directory of New Hires.	2020	1,569	1,588
262a(i)(1)	42 CFR 1003.910	OIG	Penalty for each individual who violates safety and security procedures related to handling dangerous biological agents and toxins.	2020	354,859	359,053
		OIG	Penalty for any other person who violates safety and security procedures related to handling dangerous biological agents and toxins.	2020	709,720	718,109
300jj-51		OIG	Penalty per violation for committing information blocking.	2020	1,082,016	1,094,805
1320a-7a(a)	42 CFR 1003.210(a)(1)	OIG	Penalty for knowingly presenting or causing to be presented to an officer, employee, or agent of the United States a false claim.	2020	20,866	21,113
		OIG	Penalty for knowingly presenting or causing to be presented a request for payment which violates the terms of an assignment, agreement, or PPS agreement.	2020	20,866	21,113
	42 CFR 1003.210(a)(2)	OIG	Penalty for knowingly giving or causing to be presented to a participating provider or supplier false or misleading information that could reasonably be expected to influence a discharge decision.	2020	31,300	31,670
	42 CFR 1003.210(a)(3)	OIG	Penalty for an excluded party retaining ownership or control interest in a participating entity.	2020	20,866	21,113
	42 CFR 1003.1010	OIG	Penalty for remuneration offered to induce program beneficiaries to use particular providers, practitioners, or suppliers.	2020	20,866	21,113
	42 CFR 1003.210(a)(4)	OIG	Penalty for employing or contracting with an excluded individual.	2020	20,866	21,113
	42 CFR 1003.310(a)(3)	OIG	Penalty for knowing and willful solicitation, receipt, offer, or payment of remuneration for referring an individual for a service or for purchasing, leasing, or ordering an item to be paid for by a Federal health care program.	2020	104,330	105,563
	42 CFR 1003.210(a)(1)	OIG	Penalty for ordering or prescribing medical or other item or service during a period in which the person was excluded.	2020	20,866	21,113
	42 CFR 1003.210(a)(6)	OIG	Penalty for knowingly making or causing to be made a false statement, omission or misrepresentation of a material fact in any application, bid, or contract to participate or enroll as a provider or supplier.	2020	104,330	105,563
	42 CFR 1003.210(a)(8)	OIG	Penalty for knowing of an overpayment and failing to report and return.	2020	20,866	21,113
	42 CFR 1003.210(a)(7)	OIG	Penalty for making or using a false record or statement that is material to a false or fraudulent claim.	2020	58,832	59,527

U.S.C. Section(s)	CFR <sup>1</sup>	HHS Agency	Description <sup>2</sup>	Date of Last Penalty Figure or Adjustment <sup>3</sup>	2020 Maximum Adjusted Penalty (in \$)	2021 Maximum Adjusted Penalty <sup>4</sup> (in \$)
	42 CFR 1003.210(a)(9)	OIG	Penalty for failure to grant timely access to HHS OIG for audits, investigations, evaluations, and other statutory functions of HHS OIG.	2020	31,300	31,670
1320a-7a(b)		OIG	Penalty for payments by a hospital or critical access hospital to induce a physician to reduce or limit services to individuals under direct care of physician or who are entitled to certain medical assistance benefits.	2020	5,216	5,278
		OIG	Penalty for physicians who knowingly receive payments from a hospital or critical access hospital to induce such physician to reduce or limit services to individuals under direct care of physician or who are entitled to certain medical assistance benefits.	2020	5,216	5,278
	42 CFR 1003.210(a)(10)	OIG	Penalty for a physician who executes a document that falsely certifies home health needs for Medicare beneficiaries.	2020	10,433	10,556
1320a-7a(o)		OIG	Penalty for knowingly presenting or causing to be presented a false or fraudulent specified claim under a grant, contract, or other agreement for which the Secretary provides funding.	2020	10,176	10,296
		OIG	Penalty for knowingly making, using, or causing to be made or used any false statement, omission, or misrepresentation of a material fact in any application, proposal, bid, progress report, or other document required to directly or indirectly receive or retain funds provided pursuant to grant, contract, or other agreement.	2020	50,882	51,483
		OIG	Penalty for Knowingly making, using, or causing to be made or used, a false record or statement material to a false or fraudulent specified claim under grant, contract, or other agreement.	2020	50,882	51,483
		OIG	Penalty for knowingly making, using, or causing to be made or used, a false record or statement material to an obligation to pay or transmit funds or property with respect to grant, contract, or other agreement, or knowingly conceals or improperly avoids or decreases any such obligation.	2020		
			Maximum for each false record statement		53,231	53,772
			Maximum per day		10,646	10,646
		OIG	Penalty for failure to grant timely access, upon reasonable request, to the I.G. for purposes of audits, investigations, evaluations, or other statutory functions of I.G. in matters involving grants, contracts, or other agreements.	2020	15,265	15,445
1320a-7e(b)(6)(A)	42 CFR 1003.810	OIG	Penalty for failure to report any final adverse action taken against a health care provider, supplier, or practitioner	2020	39,811	40,282
1320b-10(b)(1)	42 CFR 1003.610(a)	OIG	Penalty for the misuse of words, symbols, or emblems in communications in a manner in which a person could falsely construe that such item is approved, endorsed, or authorized by HHS	2020	10,705	10,832
1320b-10(b)(2)	42 CFR 1003.610(a)	OIG	Penalty for the misuse of words, symbols, or emblems in a broadcast or telecast in a manner in which a person could falsely construe that such item is approved, endorsed, or authorized by HHS	2020	53,524	54,157
1395i-3(b)(3)(B)(ii)(1)	42 CFR 1003.210(a)(11)	OIG	Penalty for certification of a false statement in assessment of functional capacity of a Skilled Nursing Facility resident assessment	2020	2,233	2,259
1395i-3(b)(3)(B)(ii)(2)	42 CFR 1003.210(a)(11)	OIG	Penalty for causing another to certify or make a false statement in assessment of functional capacity of a Skilled Nursing Facility resident assessment	2020	11,160	11,292
1395i-3(g)(2)(A)	42 CFR 1003.1310	OIG	Penalty for any individual who notifies or causes to be notified a Skilled Nursing Facility of the time or date on which a survey is to be conducted	2020	4,465	4,518
1395w-27(g)(2)(A)	42 CFR 1003.410	OIG	Penalty for a Medicare Advantage organization that substantially fails to provide medically necessary, required items and services	2020	40,640	41,120
		OIG	Penalty for a Medicare Advantage organization that charges excessive premiums.	2020	39,811	40,282
		OIG	Penalty for a Medicare Advantage organization that improperly expels or refuses to reenroll a beneficiary.	2020	39,811	40,282
		OIG	Penalty for a Medicare Advantage organization that engages in practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	2020	159,248	161,130
		OIG	Penalty per individual who does not enroll as a result of a Medicare Advantage organization's practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	2020	23,887	24,169
		OIG	Penalty for a Medicare Advantage organization misrepresenting or falsifying information to Secretary.	2020	159,248	161,130
		OIG	Penalty for a Medicare Advantage organization misrepresenting or falsifying information to individual or other entity.	2020	39,811	40,282
		OIG	Penalty for Medicare Advantage organization interfering with provider's advice to enrollee and non-MCO affiliated providers that balance bill enrollees.	2020	39,811	40,282

U.S.C. Section(s)	CFR <sup>1</sup>	HHS Agency	Description <sup>2</sup>	Date of Last Penalty Figure or Adjustment <sup>3</sup>	2020 Maximum Adjusted Penalty (in \$)	2021 Maximum Adjusted Penalty <sup>4</sup> (in \$)
		OIG	Penalty for a Medicare Advantage organization that employs or contracts with excluded individual or entity.	2020	39,811	40,282
		OIG	Penalty for a Medicare Advantage organization enrolling an individual in without prior written consent.	2020	39,811	40,282
		OIG	Penalty for a Medicare Advantage organization transferring an enrollee to another plan without consent or solely for the purpose of earning a commission.	2020	39,811	40,282
		OIG	Penalty for a Medicare Advantage organization failing to comply with marketing restrictions or applicable implementing regulations or guidance.	2020	39,811	40,282
		OIG	Penalty for a Medicare Advantage organization employing or contracting with an individual or entity who violates 1395w-27(g)(1)(A)-(J).	2020	39,811	40,282
1395w-141(i)(3)		OIG	Penalty for a prescription drug card sponsor that falsifies or misrepresents marketing materials, overcharges program enrollees, or misuse transitional assistance funds	2020	13,910	14,074
1395cc(g)		OIG	Penalty for improper billing by Hospitals, Critical Access Hospitals, or Skilled Nursing Facilities	2020	5,411	5,475
1395dd(d)(1)	42 CFR 1003.510	OIG	Penalty for a hospital with 100 beds or more or responsible physician dumping patients needing emergency medical care.	2020	111,597	112,916
			Penalty for a hospital with less than 100 beds dumping patients needing emergency medical care.	2020	55,800	56,460
1395mm(i)(6)(B)(i)	42 CFR 1003.410	OIG	Penalty for an HMO or competitive medical plan is such plan substantially fails to provide medically necessary, required items or services	2020	55,800	56,460
		OIG	Penalty for HMOs/competitive medical plans that charge premiums in excess of permitted amounts.	2020	55,800	56,460
		OIG	Penalty for an HMO or competitive medical plan that expels or refuses to reenroll an individual per prescribed conditions.	2020	55,800	56,460
		OIG	Penalty for an HMO or competitive medical plan that implements practices to discourage enrollment of individuals needing services in future.	2020	223,196	225,834
		OIG	Penalty per individual not enrolled in a plan as a result of a HMO or competitive medical plan that implements practices to discourage enrollment of individuals needing services in the future.	2020	32,115	32,495
		OIG	Penalty for a HMO or competitive medical plan that misrepresents or falsifies information to the Secretary.	2020	223,196	225,834
		OIG	Penalty for an HMO or competitive medical plan that misrepresents or falsifies information to an individual or any other entity.	2020	55,800	56,460
		OIG	Penalty for failure by HMO or competitive medical plan to assure prompt payment of Medicare risk sharing contracts or incentive plan provisions.	2020	55,800	56,460
		OIG	Penalty for HMO that employs or contracts with excluded individual or entity.	2020	51,222	51,827
1395nn(g)(3)	42 CFR 1003.310	OIG	Penalty for submitting or causing to be submitted claims in violation of the Stark Law's restrictions on physician self-referrals	2020	25,820	26,125
1395nn(g)(4)	42 CFR 1003.310	OIG	Penalty for circumvention schemes in violation of the Stark Law's restrictions on physician self-referrals	2020	172,137	174,172
1395ss(d)(1)	42 CFR 1003.1110	OIG	Penalty for a material misrepresentation regarding Medigap compliance policies	2020	10,705	10,832
1395ss(d)(2)	42 CFR 1003.1110	OIG	Penalty for selling Medigap policy under false pretense	2020	10,705	10,832
1395ss(d)(3)(A)(ii)	42 CFR 1003.1110	OIG	Penalty for an issuer that sells health insurance policy that duplicates benefits	2020	48,192	48,762
		OIG	Penalty for someone other than issuer that sells health insurance that duplicates benefits.	2020	28,914	29,256
1395ss(d)(4)(A)	42 CFR 1003.1110	OIG	Penalty for using mail to sell a non-approved Medigap insurance policy	2020	10,705	10,832
1396b(m)(5)(B)(i)	42 CFR 1003.410	OIG	Penalty for a Medicaid MCO that substantially fails to provide medically necessary, required items or services	2020	53,524	54,157
		OIG	Penalty for a Medicaid MCO that charges excessive premiums.	2020	53,524	54,157
		OIG	Penalty for a Medicaid MCO that improperly expels or refuses to reenroll a beneficiary.	2020	214,097	216,628
		OIG	Penalty per individual who does not enroll as a result of a Medicaid MCO's practice that would reasonably be expected to have the effect of denying or discouraging enrollment.	2020	32,115	32,495
		OIG	Penalty for a Medicaid MCO misrepresenting or falsifying information to the Secretary.	2020	214,097	216,628
		OIG	Penalty for a Medicaid MCO misrepresenting or falsifying information to an individual or another entity.	2020	53,524	54,157
		OIG	Penalty for a Medicaid MCO that fails to comply with contract requirements with respect to physician incentive plans.	2020	48,192	48,762
1396r(b)(3)(B)(ii)(I)	42 CFR 1003.210(a)(11)	OIG	Penalty for willfully and knowingly certifying a material and false statement in a Skilled Nursing Facility resident assessment	2020	2,233	2,259
1396r(b)(3)(B)(ii)(II)	42 CFR 1003.210(a)(11)	OIG	Penalty for willfully and knowingly causing another individual to certify a material and false statement in a Skilled Nursing Facility resident assessment	2020	11,160	11,292

U.S.C. Section(s)	CFR <sup>1</sup>	HHS Agency	Description <sup>2</sup>	Date of Last Penalty Figure or Adjustment <sup>3</sup>	2020 Maximum Adjusted Penalty (in \$)	2021 Maximum Adjusted Penalty <sup>4</sup> (in \$)
1396r(g)(2)(A)(i)	42 CFR 1003.1310	OIG	Penalty for notifying or causing to be notified a Skilled Nursing Facility of the time or date on which a survey is to be conducted	2020	4,465	4,518
1396r-8(b)(3)(B)	42 CFR 1003.1210	OIG	Penalty for the knowing provision of false information or refusing to provide information about charges or prices of a covered outpatient drug	2020	192,768	195,047
1396r-8(b)(3)(C)(i)	42 CFR 1003.1210	OIG	Penalty per day for failure to timely provide information by drug manufacturer with rebate agreement	2020	19,277	19,505
1396r-8(b)(3)(C)(ii)	42 CFR 1003.1210	OIG	Penalty for knowing provision of false information by drug manufacturer with rebate agreement	2020	192,768	195,047
1396t(i)(3)(A)	42 CFR 1003.1310	OIG	Penalty for notifying home and community-based providers or settings of survey	2020	3,855	3,901
11131(c)	42 CFR 1003.810	OIG	Penalty for failing to report a medical malpractice claim to National Practitioner Data Bank	2020	23,331	23,607
11137(b)(2)	42 CFR 1003.810	OIG	Penalty for breaching confidentiality of information reported to National Practitioner Data Bank	2020	23,331	23,607
299b-22(f)(1)	42 CFR 3.404	OCR	Penalty for violation of confidentiality provision of the Patient Safety and Quality Improvement Act	2020	12,919	13,072
	45 CFR 160.404(b)(1)(i) and (ii)	OCR	Penalty for each pre-February 18, 2009 violation of the HIPAA administrative simplification provisions	2020	162	64
			Calendar Year Cap	2020	40,640	41,120
1320(d)-5(a)	45 CFR 160.404(b)(2)(i)(A), (B)	OCR	Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the covered entity or business associate did not know and by exercising reasonable diligence, would not have known that the covered entity or business associate violated such a provision:	2020		
			Minimum	2020	119	120
			Maximum	2020	59,522	60,226
			Calendar Year Cap	2020	1,785,651	1,806,757
	45 CFR 160.404(b)(2)(ii)(A), (B)	OCR	Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the violation was due to reasonable cause and not to willful neglect:	2020		
			Minimum	2020	1,191	1,205
			Maximum	2020	59,522	60,226
			Calendar Year Cap	2020	1,785,651	1,806,757
	45 CFR 160.404(b)(2)(iii)(A), (B)	OCR	Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the violation was due to willful neglect and was corrected during the 30-day period beginning on the first date the covered entity or business associate knew, or, by exercising reasonable diligence, would have known that the violation occurred:	2020		
			Minimum	2020	11,904	12,045
			Maximum	2020	59,522	60,226
			Calendar Year Cap	2020	1,785,651	1,806,757
	45 CFR 160.404(b)(2)(iv)(A), (B)	OCR	Penalty for each February 18, 2009 or later violation of a HIPAA administrative simplification provision in which it is established that the violation was due to willful neglect and was not corrected during the 30-day period beginning on the first date the covered entity or business associate knew, or by exercising reasonable diligence, would have known that the violation occurred:	2020		
			Minimum	2020	59,522	60,226
			Maximum	2020	1,785,651	1,806,757
			Calendar Year Cap	2020	1,785,651	1,806,757
42 U.S.C. 300gg-18, 42 U.S.C. 1302	45 CFR 180.90	CMS	Penalty for a hospital's non-compliance with making public standard charges for hospital items and services	2020		
			Per Day (Maximum)	2020	300	304
CARES Act, Pub. L. 116-136, section 3202(b)(2)	(See 85 FR 71142 November 6, 2020)	CMS	Penalty for a provider's non-compliance with price transparency requirements regarding diagnostic tests for COVID-19	2020		-
			Per Day (Maximum)	2020	-	-
263a(h)(2)(B) & 1395w-2(b)(2)(A)(ii)	42 CFR 493.1834(d)(2)(i).	CMS	Penalty for a clinical laboratory's failure to meet participation and certification requirements and poses immediate jeopardy:	2020		
			Minimum	2020	6,530	6,607
			Maximum	2020	21,410	21,663



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	42 CFR 493.1834(d)(2)(ii).	CMS	Penalty for a clinical laboratory's failure to meet participation and certification requirements and the failure does not pose immediate jeopardy:	2020		
			Minimum	2020	108	109
			Maximum	2020	6,422	6,498
	42 CFR 493.1834(d)(2)(iii)	CMS	Penalty for a clinical laboratory's failure to meet SARS-CoV-2 test reporting requirements:	2020	N/A	
			First day of noncompliance.	2020	N/A	
			Each additional day of noncompliance.	2020	N/A	
300gg-15(f)	45 CFR 147.200(e)	CMS	Failure to provide the Summary of Benefits and Coverage.	2020	1,176	1,190
300gg-18	45 CFR 158.606	CMS	Penalty for violations of regulations related to the medical loss ratio reporting and rebating	2020	118	119
	45 CFR 180.90	CMS	Price against hospital identified by CMS as noncompliant according to 45 CFR 182.50 with respect to price transparency requirements regarding diagnostic tests for COVID-19.	2020		
			Maximum penalty per day	2020	Effective 2021	
1320a-7h(b)(1)	42 CFR 402.105(d)(5) and 403.912(a) and (c)	CMS	Penalty for manufacturer or group purchasing organization failing to report information required under 42 U.S.C. 1320a-7h(a), relating to physician ownership or investment interests:	2020		
			Minimum	2020	1,176	1,190
			Maximum	2020	11,766	11,905
			Calendar Year Cap	2020	176,495	178,581
1320a-7h(b)(2)	42 CFR 402.105(h) and 403.912(b) and (c)	CMS	Penalty for manufacturer or group purchasing organization knowingly failing to report information required under 42 U.S.C. 1320a-7h(a), relating to physician ownership or investment interests:	2020		
			Minimum	2020	11,766	11,905
			Maximum	2020	117,664	119,055
			Calendar Year Cap	2020	1,176,638	1,190,546
		CMS	Penalty for an administrator of a facility that fails to comply with notice requirements for the closure of a facility.	2020	117,664	119,055
1320a-7j(h)(3)(A)	42 CFR 488.446(a)(1), (2), & (3)	CMS	Minimum penalty for the first offense of an administrator who fails to provide notice of facility closure.	2020	588	595
			Minimum penalty for the second offense of an administrator who fails to provide notice of facility closure.	2020	1,766	1,787
			Minimum penalty for the third and subsequent offenses of an administrator who fails to provide notice of facility closure.	2020	3,529	3,571
1320a-8(a)(1)		CMS	Penalty for an entity knowingly making a false statement or representation of material fact in the determination of the amount of benefits or payments related to old-age, survivors, and disability insurance benefits, special benefits for certain World War II veterans, or supplemental security income for the aged, blind, and disabled.	2020	8,606	8,708
			Penalty for violation of 42 U.S.C. 1320a-8(a)(1) if the violator is a person who receives a fee or other income for services performed in connection with determination of the benefit amount or the person is a physician or other health care provider who submits evidence in connection with such a determination.	2020	8,116	8,212
1320a-8(a)(3)		CMS	Penalty for a representative payee (under 42 U.S.C. 405(j), 1007, or 1383(a)(2)) converting any part of a received payment from the benefit programs described in the previous civil monetary penalty to a use other than for the benefit of the beneficiary.	2020	6,740	6,820
1320b-25(c)(1)(A)		CMS	Penalty for failure of covered individuals to report to the Secretary and 1 or more law enforcement officials any reasonable suspicion of a crime against a resident, or individual receiving care, from a long-term care facility.	2020	235,328	238,110
1320b-25(c)(2)(A)		CMS	Penalty for failure of covered individuals to report to the Secretary and 1 or more law enforcement officials any reasonable suspicion of a crime against a resident, or individual receiving care, from a long-term care facility if such failure exacerbates the harm to the victim of the crime or results in the harm to another individual.	2020	352,991	357,163
1320b-25(d)(2)		CMS	Penalty for a long-term care facility that retaliates against any employee because of lawful acts done by the employee, or files a complaint or report with the State professional disciplinary agency against an employee or nurse for lawful acts done by the employee or nurse.	2020	235,328	238,110
1395b-7(b)(2)(B)	42 CFR 402.105(g)	CMS	Penalty for any person who knowingly and willfully fails to furnish a beneficiary with an itemized statement of items or services within 30 days of the beneficiary's request.	2020	159	161

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1395i-3(h)(2)(B)(ii)(I)	42 CFR 488.408(d)(1)(iii)	CMS	Penalty per day for a Skilled Nursing Facility that has a Category 2 violation of certification requirements:	2020		
			Minimum	2020	112	113
			Maximum	2020	6,695	6,774
	42 CFR 488.408(d)(1)(iv)	CMS	Penalty per instance of Category 2 noncompliance by a Skilled Nursing Facility:	2020		
			Minimum	2020	2,233	2,259
			Maximum	2020	22,320	22,584
	42 CFR 488.408(e)(1)(iii)	CMS	Penalty per day for a Skilled Nursing Facility that has a Category 3 violation of certification requirements:	2020		
			Minimum	2020	6,808	6,888
			Maximum	2020	22,320	22,584
	42 CFR 488.408(e)(1)(iv)	CMS	Penalty per instance of Category 3 noncompliance by a Skilled Nursing Facility:	2020		
			Minimum	2020	2,233	2,259
			Maximum	2020	22,320	22,584
	42 CFR 488.408(e)(2)(ii)	CMS	Penalty per day and per instance for a Skilled Nursing Facility that has Category 3 noncompliance with Immediate Jeopardy:	2020		
			Per Day (Minimum)	2020	6,808	6,888
			Per Day (Maximum)	2020	22,320	22,584
			Per Instance (Minimum)	2020	2,233	2,259
			Per Instance (Maximum)	2020	22,320	22,584
	42 CFR 488.438(a)(1)(i)	CMS	Penalty per day of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the upper range per day:	2020		
			Minimum	2020	6,808	6,888
			Maximum	2020	22,320	22,584
	42 CFR 488.438(a)(1)(ii)	CMS	Penalty per day of a Skilled Nursing Facility that fails to meet certification requirements. These amounts represent the lower range per day:	2020		
			Minimum	2020	112	113
			Maximum	2020	6,695	6,774
	42 CFR 488.438(a)(2)	CMS	Penalty per instance of a Skilled Nursing Facility that fails to meet certification requirements:	2020		
			Minimum	2020	2,233	2,259
			Maximum	2020	22,320	22,584
	42 CFR 488.447	CMS	Penalty imposed for failure to comply with infection control weekly reporting requirements at 42 CFR 483.80(g)(1) and (2).	2020		
			First occurrence	2020	1,000	1,012
			Incremental increases for each subsequent occurrence.	2020	500	506
1395l(h)(5)(D)	42 CFR 402.105(d)(2)(i)	CMS	Penalty for knowingly, willfully, and repeatedly billing for a clinical diagnostic laboratory test other than on an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 42 U.S.C. 320a-7a(a).)	2020	16,257	16,449
1395l(i)(6)		CMS	Penalty for knowingly and willfully presenting or causing to be presented a bill or request for payment for an intraocular lens inserted during or after cataract surgery for which the Medicare payment rate includes the cost of acquiring the class of lens involved.	2020	4,282	4,333
1395l(q)(2)(B)(i)	42 CFR 402.105(a)	CMS	Penalty for knowingly and willfully failing to provide information about a referring physician when seeking payment on an unassigned basis.	2020	4,098	4,146
1395m(a)(11)(A)	42 CFR 402.1(c)(4) and 402.105(d)(2)(ii)	CMS	Penalty for any durable medical equipment supplier that knowingly and willfully charges for a covered service that is furnished on a rental basis after the rental payments may no longer be made. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 42 U.S.C. 1320a-7a(a).)	2020	16,257	16,449

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1395m(a)(18)(B)	42 CFR 402.1(c)(5) and 402.105(d)(2)(iii)	CMS	Penalty for any nonparticipating durable medical equipment supplier that knowingly and willfully fails to make a refund to Medicare beneficiaries for a covered service for which payment is precluded due to an unsolicited telephone contact from the supplier. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 42 U.S.C. 320a-7a(a).)	2020	16,257	16,449
1395m(b)(5)(C)	42 CFR 402.1(c)(6) and 402.105(d)(2)(iv)	CMS	Penalty for any nonparticipating physician or supplier that knowingly and willfully charges a Medicare beneficiary more than the limiting charge for radiologist services. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a).)	2020	16,257	16,449
1395m(h)(3)	42 CFR 402.1(c)(8) and 402.105(d)(2)(vi)	CMS	Penalty for any supplier of prosthetic devices, orthotics, and prosthetics that knowingly and willfully charges for a covered prosthetic device, orthotic, or prosthetic that is furnished on a rental basis after the rental payment may no longer be made. (Penalties are assessed in the same manner as 42 U.S.C. 1395m(a)(11)(A), that is in the same manner as 42 U.S.C. 395u(j)(2)(B), which is assessed according to 42 U.S.C. 1320a-7a(a).)	2020	16,257	16,449
1395m(j)(2)(A)(iii)		CMS	Penalty for any supplier of durable medical equipment including a supplier of prosthetic devices, prosthetics, orthotics, or supplies that knowingly and willfully distributes a certificate of medical necessity in violation of section 1834(j)(2)(A)(i) of the Act or fails to provide the information required under section 1834(j)(2)(A)(ii) of the Act.	2020	1,722	1,742
1395m(j)(4)	42 CFR 402.1(c)(10) and 402.105(d)(2)(vii)	CMS	Penalty for any supplier of durable medical equipment, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries for series billed other than on an assignment-related basis under certain conditions. (Penalties are assessed in the same manner as 42 U.S.C. 1395m(j)(4) and 1395u(j)(2)(B), which is assessed according to 42 U.S.C. 1320a-7a(a).)	2020	16,257	16,449
1395m-1(a)	42 CFR 414.504(e)	CMS	Penalty for an applicable entity that has failed to report or made a misrepresentation or omission in reporting applicable information with respect to a clinical diagnostic laboratory test.	2020	10,839	10,967
	42 CFR 402.1(c)(31) and 402.105(d)(3)	CMS	Penalty for any person or entity who knowingly and willfully bills or collects for any outpatient therapy services or comprehensive outpatient rehabilitation services on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395m(k)(6) and 1395u(j)(2)(B), which is assessed according to 42 U.S.C. 1320a-7a(a).)	2020	16,257	16,449
1395m(l)(6)	42 CFR 402.1(c)(32) and 402.105(d)(4)	CMS	Penalty for any supplier of ambulance services who knowingly and willfully fills or collects for any services on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(b)(18)(B), which is assessed according to 1320a-7a(a).)	2020	16,257	16,449
1395u(b)(18)(B)	42 CFR 402.1(c)(11) and 402.105(d)(2)(viii)	CMS	Penalty for any practitioner specified in Section 1842(b)(18)(C) of the Act or other person that knowingly and willfully bills or collects for any services by the practitioners on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 42 U.S.C. 1320a-7a(a).)	2020	16,257	16,449
1395u(j)(2)(B)	42 CFR 402.1(c)	CMS	Penalty for any physician who charges more than 125% for a non-participating referral. (Penalties are assessed in the same manner as 42 U.S.C. 1320a-7a(a).)	2020	16,257	16,449
1395u(k)	42 CFR 402.1(c)(12), 402.105(d)(2)(ix), section 1834A(a)(9) of the Act, and 42 CFR 414.504(e)	CMS	Penalty for any physician who knowingly and willfully presents or causes to be presented a claim for bill for an assistant at a cataract surgery performed on or after March 1, 1987, for which payment may not be made because of section 1862(a)(15) of the Act. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 42 U.S.C. 1320a-7a(a).)	2020	16,257	16,449
1395u(l)(3)	42 CFR 402.1(c)(13) and 402.105(d)(2)(x)	CMS	Penalty for any nonparticipating physician who does not accept payment on an assignment-related basis and who knowingly and willfully fails to refund on a timely basis any amounts collected for services that are not reasonable or medically necessary or are of poor quality under 1842(l)(1)(A). (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 42 U.S.C. 1320a-7a(a).)	2020	16,257	16,449
1395u(m)(3)	42 CFR 402.1(c)(14) and 402.105(d)(2)(xi)	CMS	Penalty for any nonparticipating physician charging more than \$500 who does not accept payment for an elective surgical procedure on an assignment related basis and who knowingly and willfully fails to disclose the required information regarding charges and coinsurance amounts and fails to refund on a timely basis any amount collected for the procedure in excess of the charges recognized and approved by the Medicare program. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 42 U.S.C. 1320a-7a(a).)	2020	16,257	16,449

U.S.C. Section(s)	CFR <sup>1</sup>	HHS Agency	Description <sup>2</sup>	Date of Last Penalty Figure or Adjustment <sup>3</sup>	2020 Maximum Adjusted Penalty (in \$)	2021 Maximum Adjusted Penalty <sup>4</sup> (in \$)
1395u(n)(3)	42 CFR 402.1(c)(15) and 402.105(d)(2)(xii)	CMS	Penalty for any physician who knowingly, willfully, and repeatedly bills one or more beneficiaries for purchased diagnostic tests any amount other than the payment amount specified by the Act. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 1320a-7a(a))	2020	16,257	16,449
1395u(o)(3)(B)	42 CFR 414.707(b)	CMS	Penalty for any practitioner specified in Section 1842(b)(18)(C) of the Act or other person that knowingly and willfully bills or collects for any services pertaining to drugs or biologics by the practitioners on other than an assignment-related basis. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(b)(18)(B) and 1395u(j)(2)(B), which is assessed according to 42 U.S.C. 1320a-7a(a).)	2020	16,257	16,449
1395u(p)(3)(A)		CMS	Penalty for any physician or practitioner who knowingly and willfully fails promptly to provide the appropriate diagnosis codes upon CMS or Medicare administrative contractor request for payment or bill not submitted on an assignment-related basis.	2020	4,282	4,333
1395w-3a(d)(4)(A)	42 CFR 414.806	CMS	Penalty for a pharmaceutical manufacturer's misrepresentation of average sales price of a drug, or biologic.	2020	13,910	14,074
1395w-4(g)(1)(B)	42 CFR 402.1(c)(17) and 402.105(d)(2)(xiii)	CMS	Penalty for any nonparticipating physician, supplier, or other person that furnishes physician services not on an assignment-related basis who either knowingly and willfully bills or collects in excess of the statutorily-defined limiting charge or fails to make a timely refund or adjustment. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 42 U.S.C. 1320a-7a(a).)	2020	16,257	16,449
1395w-4(g)(3)(B)	42 CFR 402.1(c)(18) and 402.105(d)(2)(xiv)	CMS	Penalty for any person that knowingly and willfully bills for statutorily defined State-plan approved physicians' services on any other basis than an assignment-related basis for a Medicare/Medicaid dual eligible beneficiary. (Penalties are assessed in the same manner as 42 U.S.C. 1395u(j)(2)(B), which is assessed according to 42 U.S.C. 1320a-7a(a).)	2020	16,257	16,449
1395w-27(g)(3)(A); 1857(g)(3); 1860D-12(b)(3)(E)	42 CFR 422.760(b) and 423.760(b)	CMS	Penalty for each termination determination the Secretary makes that is the result of actions by a Medicare Advantage organization or Part D sponsor that has adversely affected (or has the substantial likelihood of adversely affecting) an individual covered under the organization's contract.	2020	39,811	40,282
1395w-27(g)(3)(B); 1857(g)(3); 1860D-12(b)(3)(E)		CMS	Penalty for each week beginning after the initiation of civil money penalty procedures by the Secretary because a Medicare Advantage organization or Part D sponsor has failed to carry out a contract, or has carried out a contract inconsistently with regulations.	2020	15,925	16,113
1395w-27(g)(3)(D); 1857(g)(3); 1860D-12(b)(3)(E)		CMS	Penalty for a Medicare Advantage organization's or Part D sponsor's early termination of its contract.	2020	147,889	149,637
1395y(b)(3)(C)	42 CFR 411.103(b)	CMS	Penalty for an employer or other entity to offer any financial or other incentive for an individual entitled to benefits not to enroll under a group health plan or large group health plan which would be a primary plan.	2020	9,639	9,753
1395y(b)(5)(C)(ii)	42 CFR 402.1(c)(20) and 402.105(b)(2)	CMS	Penalty for any non-governmental employer that, before October 1, 1998, willfully or repeatedly failed to provide timely and accurate information requested relating to an employee's group health insurance coverage.	2020	1,569	1,588
1395y(b)(6)(B)	42 CFR 402.1(c)(21) and 402.105(a)	CMS	Penalty for any entity that knowingly, willfully, and repeatedly fails to complete a claim form relating to the availability of other health benefits in accordance with statute or provides inaccurate information relating to such on the claim form.	2020	3,443	3,484
1395y(b)(7)(B)(i)		CMS	Penalty for any entity serving as insurer, third party administrator, or fiduciary for a group health plan that fails to provide information that identifies situations where the group health plan is or was a primary plan to Medicare to the HHS Secretary.	2020	1,232	1,247
1395y(b)(8)(E)		CMS	Penalty for any non-group health plan that fails to identify claimants who are Medicare beneficiaries and provide information to the HHS Secretary to coordinate benefits and pursue any applicable recovery claim.	2020	1,232	1,247
1395nn(g)(5)	42 CFR 411.361	CMS	Penalty for any person that fails to report information required by HHS under section 1877(f) of the Act concerning ownership, investment, and compensation arrangements.	2020	20,489	20,731
1395pp(h)	42 CFR 402.1(c)(23) and 402.105(d)(2)(xv)	CMS	Penalty for any durable medical equipment supplier, including a supplier of prosthetic devices, prosthetics, orthotics, or supplies, that knowingly and willfully fails to make refunds in a timely manner to Medicare beneficiaries under certain conditions. (42 U.S.C. 1395(m)(18) sanctions apply here in the same manner, which is under 42 U.S.C. 1395u(j)(2) and 1320a-7a(a)).	2020	16,257	16,449
1395ss(a)(2)	42 CFR 402.1(c)(24) and 405.105(f)(1)	CMS	Penalty for any person that issues a Medicare supplemental policy that has not been approved by the State regulatory program or does not meet Federal standards after a statutorily defined effective date.	2020	55,799	56,459
1395ss(d)(3)(A)(vi)(II)	42 CFR 402.1(c)(25) and 402.105(e) and (f)(2)	CMS	Penalty for someone other than issuer that sells or issues a Medicare supplemental policy to beneficiary without a disclosure statement.	2020	28,914	29,256

U.S.C. Section(s)	CFR <sup>1</sup>	HHS Agency	Description <sup>2</sup>	Date of Last Penalty Figure or Adjustment <sup>3</sup>	2020 Maximum Adjusted Penalty (in \$)	2021 Maximum Adjusted Penalty <sup>4</sup> (in \$)
		CMS	Penalty for an issuer that sells or issues a Medicare supplemental policy without disclosure statement.	2020	48,192	48,762
1395ss(d)(3)(B)(iv)		CMS	Penalty for someone other than issuer that sells or issues a Medicare supplemental policy without acknowledgement form.	2020	28,914	29,256
		CMS	Penalty for issuer that sells or issues a Medicare supplemental policy without an acknowledgement form.	2020	48,192	48,762
1395ss(p)(8)	42 CFR 402.1(c)(25) and 402.105(e)	CMS	Penalty for someone other than issuer that sells or issues Medicare supplemental policies after a given date that fail to conform to the NAIC or Federal standards established by statute.	2020	28,914	29,256
	42 CFR 402.1(c)(25) and 402.105(f)(2)	CMS	Penalty for an issuer that sells or issues Medicare supplemental policies after a given date that fail to conform to the NAIC or Federal standards established by statute.	2020	48,192	48,762
1395ss(p)(9)(C)	42 CFR 402.1(c)(26), 402.105(e), 402.105(f)(3), (4)	CMS	Penalty for someone other than issuer that sells a Medicare supplemental policy and fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits or fails to provide the individual, before selling the policy, an outline of coverage describing benefits.	2020	28,914	29,256
	42 CFR 402.1(c)(26), 402.105(f)(3), (4)	CMS	Penalty for an issuer that sells a Medicare supplemental policy and fails to make available for sale the core group of basic benefits when selling other Medicare supplemental policies with additional benefits or fails to provide the individual, before selling the policy, an outline of coverage describing benefits.	2020	48,192	48,762
1395ss(q)(5)(C)	42 CFR 402.1(c)(27) and 402.105(f)(5)	CMS	Penalty for any person that fails to suspend the policy of a policyholder made eligible for medical assistance or automatically reinstates the policy of a policyholder who has lost eligibility for medical assistance, under certain circumstances.	2020	48,192	48,762
1395ss(r)(6)(A)	42 CFR 402.1(c)(28) and 402.105(f)(6)	CMS	Penalty for any person that fails to provide refunds or credits as required by section 1882(r)(1)(B) of the Act.	2020	48,192	48,762
1395ss(s)(4)	42 CFR 402.1(c)(29) and 402.105(c)	CMS	Penalty for any issuer of a Medicare supplemental policy that does not waive listed time periods if they were already satisfied under a proceeding Medicare supplemental policy, or denies a policy, or conditions the issuances or effectiveness of the policy, or discriminates in the pricing of the policy base on health status or other specified criteria.	2020	20,459	20,701
1395ss(t)(2)	42 CFR 402.1(c)(30) and 402.105(f)(7)	CMS	Penalty for any issuer of a Medicare supplemental policy that fails to fulfill listed responsibilities.	2020	48,192	48,762
1395ss(v)(4)(A)		CMS	Penalty someone other than issuer who sells, issues, or renews a Medigap Rx policy to an individual who is a Part D enrollee.	2020	20,865	21,112
		CMS	Penalty for an issuer who sells, issues, or renews a Medigap Rx policy who is a Part D enrollee.	2020	34,777	35,188
1395bbb(c)(1)	42 CFR 488.725(c)	CMS	Penalty for any individual who notifies or causes to be notified a home health agency of the time or date on which a survey of such agency is to be conducted	2020	4,465	4,518
1395bbb(f)(2)(A)(i)	42 CFR 488.845(b)(2)(iii), (b)(3) - (6), and (d)(1)(ii)	CMS	Maximum daily penalty amount for each day a home health agency is not in compliance with statutory requirements	2020	21,410	21,663
	42 CFR 488.845(b)(3)	CMS	Penalty per day for home health agency's noncompliance (Upper Range):	2020		0
			Minimum	2020	18,198	18,413
			Maximum	2020	21,410	21,663
	42 CFR 488.845(b)(3)(i)	CMS	Penalty for a home health agency's deficiency or deficiencies that cause immediate jeopardy and result in actual harm	2020	21,410	21,663
	42 CFR 488.845(b)(3)(ii)	CMS	Penalty for a home health agency's deficiency or deficiencies that cause immediate jeopardy and result in potential for harm	2020	19,268	19,496
	42 CFR 488.845(b)(3)(iii)	CMS	Penalty for an isolated incident of noncompliance in violation of established HHA policy	2020	18,198	18,413
	42 CFR 488.845(b)(4)	CMS	Penalty for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy, but is directly related to poor quality patient care outcomes (Lower Range):	2020		
			Minimum	2020	3,213	3,251
			Maximum	2020	18,198	18,413
	42 CFR 488.845(b)(5)	CMS	Penalty for a repeat and/or condition-level deficiency that does not constitute immediate jeopardy and that is related predominately to structure or process-oriented conditions (Lower Range):	2020		
			Minimum	2020	1,071	1,084
			Maximum	2020	2,141	2,166

U.S.C. Section(s)	CFR <sup>1</sup>	HHS Agency	Description <sup>2</sup>	Date of Last Penalty Figure or Adjustment <sup>3</sup>	2020 Maximum Adjusted Penalty (in \$)	2021 Maximum Adjusted Penalty <sup>4</sup> (in \$)
	42 CFR 488.845(b)(6)	CMS	Penalty imposed for instance of noncompliance that may be assessed for one or more singular events of condition-level noncompliance that are identified and where the noncompliance was corrected during the onsite survey:	2020		
			Minimum	2020	2,141	2,166
			Maximum	2020	21,410	21,663
			Penalty for each day of noncompliance (Maximum).	2020	21,410	21,663
	42 CFR 488.845(d)(1)(ii)	CMS	Penalty for each day of noncompliance (Maximum)	2020	21,410	21,663
1395eee(e)(6)(B); 1396u-4(e)(6)(B)	42 CFR 460.46	CMS	Penalty for PACE organization that discriminates in enrollment or disenrollment, or engages in any practice that would reasonably be expected to have the effect of denying or discouraging enrollment, on the basis of health status or the need for services:	2020	39,811	40,282
		CMS	For each individual not enrolled as a result of the PACE organization's discrimination in enrollment or disenrollment or practice that would deny or discourage enrollment.	2020		
			Minimum	2020	15,000	15,177
			Maximum	2020	100,000	101,182
		CMS	Penalty for a PACE organization that charges excessive premiums.	2020	39,811	40,282
		CMS	Penalty for a PACE organization misrepresenting or falsifying information to CMS or the State.	2020	159,248	161,130
		CMS	Penalty for any other violation specified in 42 CFR 460.40.	2020	39,811	40,282
1396r(h)(3)(C)(ii)(I)	42 CFR 488.408(d)(1)(iii)	CMS	Penalty per day for a nursing facility's failure to meet a Category 2 Certification:	2020		
			Minimum	2020	112	113
			Maximum	2020	6,695	6,774
	42 CFR 488.408(d)(1)(iv)	CMS	Penalty per instance for a nursing facility's failure to meet Category 2 certification:	2020		
			Minimum	2020	2,233	2,259
			Maximum	2020	22,320	22,584
	42 CFR 488.408(e)(1)(iii)	CMS	Penalty per day for a nursing facility's failure to meet Category 3 certification:	2020		
			Minimum	2020	6,808	6,888
			Maximum	2020	22,320	22,584
	42 CFR 488.408(e)(1)(iv)	CMS	Penalty per instance for a nursing facility's failure to meet Category 3 certification:	2020		
			Minimum	2020	2,233	2,259
			Maximum	2020	22,320	22,584
	42 CFR 488.408(e)(2)(ii)	CMS	Penalty per instance for a nursing facility's failure to meet Category 3 certification, which results in immediate jeopardy:	2020		
			Minimum	2020	2,233	2,259
			Maximum	2020	22,320	22,584
	42 CFR 488.438(a)(1)(i)	CMS	Penalty per day for nursing facility's failure to meet certification (Upper Range):	2020		
			Minimum	2020	6,808	6,888
			Maximum	2020	22,320	22,584
	42 CFR 488.438(a)(1)(ii)	CMS	Penalty per day for nursing facility's failure to meet certification (Lower Range):	2020		
			Minimum	2020	112	113
			Maximum	2020	6,695	6,774
	42 CFR 488.438(a)(2)	CMS	Penalty per instance for nursing facility's failure to meet certification:	2020		
			Minimum	2020	2,233	2,259
			Maximum	2020	22,320	22,584
	42 CFR 488.447	CMS	Penalty imposed for failure to comply with infection control weekly reporting requirements at 42 CFR 483.80(g)(1) and (2)	2020		
			First occurrence (Minimum)	2020	1,000	1,012
			Incremental increases for each subsequent occurrence	2020	500	506
1396r(f)(2)(B)(iii)(I)(c)	42 CFR 483.151(b)(2)(iv) and (b)(3)(iii)	CMS	Grounds to prohibit approval of Nurse Aide Training Program—if assessed a penalty in 1819(h)(2)(B)(i) or 1919(h)(2)(A)(ii) of “not less than \$5,000” [Not CMP authority, but a specific CMP amount (CMP at this level) that is the triggering condition for disapproval]	2020	11,160	11,292

U.S.C. Section(s)	CFR <sup>1</sup>	HHS Agency	Description <sup>2</sup>	Date of Last Penalty Figure or Adjustment <sup>3</sup>	2020 Maximum Adjusted Penalty (in \$)	2021 Maximum Adjusted Penalty <sup>4</sup> (in \$)
1396r(h)(3)(C)(ii)(I)	42 CFR 483.151(c)(2)	CMS	Grounds to waive disapproval of nurse aide training program—reference to disapproval based on imposition of CMP “not less than \$5,000” [Not CMP authority but CMP imposition at this level determines eligibility to seek waiver of disapproval of nurse aide training program]	2020	11,160	11,292
1396t(j)(2)(C)		CMS	Penalty for each day of noncompliance for a home or community care provider that no longer meets the minimum requirements for home and community care:	2020		
			Minimum	2020	2	2
			Maximum	2020	19,277	19,505
1396u-2(e)(2)(A)(i)	42 CFR 438.704	CMS	Penalty for a Medicaid managed care organization that fails substantially to provide medically necessary items and services	2020	39,811	40,282
		CMS	Penalty for Medicaid managed care organization that imposes premiums or charges on enrollees in excess of the premiums or charges permitted.	2020	39,811	40,282
		CMS	Penalty for a Medicaid managed care organization that misrepresents or falsifies information to another individual or entity.	2020	39,811	40,282
		CMS	Penalty for a Medicaid managed care organization that fails to comply with the applicable statutory requirements for such organizations.	2020	39,811	40,282
1396u-2(e)(2)(A)(ii)	42 CFR 438.704	CMS	Penalty for a Medicaid managed care organization that misrepresents or falsifies information to the HHS Secretary	2020	159,248	161,130
		CMS	Penalty for Medicaid managed care organization that acts to discriminate among enrollees on the basis of their health status.	2020	159,248	161,130
1396u-2(e)(2)(A)(iv)	42 CFR 438.704	CMS	Penalty for each individual that does not enroll as a result of a Medicaid managed care organization that acts to discriminate among enrollees on the basis of their health status	2020	23,887	24,169
1396u(h)(2)	42 CFR part 441, Subpart I	CMS	Penalty for a provider not meeting one of the requirements relating to the protection of the health, safety, and welfare of individuals receiving community supported living arrangements services	2020	22,320	22,584
1396w-2(c)(1)		CMS	Penalty for disclosing information related to eligibility determinations for medical assistance programs	2020	11,904	12,045
18041(c)(2)	45 CFR 156.805(c)	CMS	Failure to comply with ACA requirements related to risk adjustment, reinsurance, risk corridors, Exchanges (including QHP standards) and other ACA Subtitle D standards; Penalty for violations of rules or standards of behavior associated with issuer compliance with risk adjustment, reinsurance, risk corridors, Exchanges (including QHP standards) and other ACA Subtitle D standards.	2020	162	164
18081(h)(1)(A)(i)(II)	45 CFR 155.285	CMS	Penalty for providing false information on Exchange application	2020	29,416	29,764
18081(h)(1)(B)	45 CFR 155.285	CMS	Penalty for knowingly or willfully providing false information on Exchange application	2020	294,159	297,636
18081(h)(2)	45 CFR 155.260	CMS	Penalty for knowingly or willfully disclosing protected information from Exchange	2020		
		CMS	Minimum	2020	29,416	29,764
		CMS	Maximum	2020	300	304
18041(c)(2)	45 CFR 155.206(i)	CMS	Penalties for violation of applicable Exchange standards by consumer assistance entities in Federally-facilitated Exchanges	2020		
			Maximum (Per Day)	2020	100	101
31 U.S.C.				2020	300	304
1352	45 CFR 93.400(e)	HHS	Penalty for the first time an individual makes an expenditure prohibited by regulations regarding lobbying disclosure, absent aggravating circumstances	2020	20,489	20,731
			Penalty for second and subsequent offenses by individuals who make an expenditure prohibited by regulations regarding lobbying disclosure:	2020		
			Minimum	2020	20,489	20,731
			Maximum	2020	204,892	207,314
		HHS	Penalty for the first time an individual fails to file or amend a lobbying disclosure form, absent aggravating circumstances	2020	20,489	20,731
			Penalty for second and subsequent offenses by individuals who fail to file or amend a lobbying disclosure form, absent aggravating circumstances:	2020		
			Minimum	2020	20,489	20,731
			Maximum	2020	204,892	207,314
	45 CFR part 93, Appendix A	HHS	Penalty for failure to provide certification regarding lobbying in the award documents for all sub-awards of all tiers:	2020		

U.S.C. Section(s)	CFR <sup>1</sup>	HHS Agency	Description <sup>2</sup>	Date of Last Penalty Figure or Adjustment <sup>3</sup>	2020 Maximum Adjusted Penalty (in \$)	2021 Maximum Adjusted Penalty <sup>4</sup> (in \$)
			Minimum	2020	20,489	20,731
			Maximum	2020	204,892	207,314
		HHS	Penalty for failure to provide statement regarding lobbying for loan guarantee and loan insurance transactions:	2020		
			Minimum	2020	20,489	20,731
			Maximum	2020	204,892	207,314
3801-3812	45 CFR 79.3(a)(1)(iv)	HHS	Penalty against any individual who—with knowledge or reason to know—makes, presents or submits a false, fictitious or fraudulent claim to the Department	2020	10,706	10,833
	45 CFR 79.3(b)(1)(ii)	HHS	Penalty against any individual who—with knowledge or reason to know—makes, presents or submits a false, fictitious or fraudulent claim to the Department	2020	10,706	10,833

<sup>1</sup> Some HHS components have not promulgated regulations regarding their civil monetary penalty-specific statutory authorities.

<sup>2</sup> The description is not intended to be a comprehensive explanation of the underlying violation; the statute and corresponding regulation, if applicable, should be consulted.

<sup>3</sup> Statutory or Inflation Act Adjustment.

<sup>4</sup> The cost of living multiplier for 2021, based on the Consumer Price Index for all Urban Consumers (CPI-U) for the month of October 2020, not seasonally adjusted, is 1.01182, as indicated in OMB Memorandum M-21-10, "Implementation of Penalty Inflation Adjustments for 2021, Pursuant to the Federal Civil Penalties Adjustment Act Improvements Act of 2015" (December 23, 2020).



Dated: November 8, 2021.

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**Xavier Becerra,**

Secretary,

Department of Health and Human Services.

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